UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF NORTH CAROLINA

Richard M. Pavelock, M.D., Plaintiff, v. Sylvia Burwell, in her official capacity as Secretary of Health and Human Services, Defendant.	Case No. 5:15-cv-101 **COMPLAINT**

BACKGROUND

Plaintiff, Richard M. Pavelock, M.D. ("Dr. Pavelock"), by and through its undersigned counsel, hereby files this Complaint against Defendant Sylvia Burwell, in her official capacity as Secretary of the United States Department of Health and Human Services (the "Secretary"). In support of his claims, Dr. Pavelock alleges the following:

This case stems from Dr. Pavelock's treatment of certain patients residing in Medicare intermediate care facilities for the mentally retarded ("ICF/MRs"). The patients at issue here have diagnoses of moderate to profound mental retardation with various secondary diagnoses. Due to these conditions, the patients are non-verbal and receive round-the-clock care from nurse-caregivers. Dr. Pavelock performed evaluation and management ("E/M") services for these patients. Because the patients are non-verbal and non-communicative, Dr. Pavelock consulted with the patients' nurse care-givers to gather the patients' medical histories. This process was functionally equivalent to taking a medical history directly from a traditional communicative patient.

Following an initial determination of overpayment on January 23, 2012, Dr. Pavelock made his way through the winding administrative appeals process. On January 9, 2015, Administrative Law Judge Steven J. Chaffin (the "ALJ") rendered a decision largely favorable to Dr. Pavelock (the "ALJ Decision II"). After considering non-binding guidance suggesting an in-person examination is required, the ALJ recognized that "because communication with [the patients] would be difficult to impossible," in these particular circumstances Dr. Pavelock could properly obtain patient histories through consultation with nurse-caregivers.

The Medicare Appeals Council (the "MAC"), in its decision dated June 5, 2015 (the "MAC Decision II," attached hereto as Exhibit 1), reverses the ALJ in part and insists that Dr. Pavelock cannot be reimbursed for E/M services when the patient's history was not gathered through a face-to-face consultation. (Protected Health Information has been redacted from Exhibit 1.) On this basis, the MAC concludes that numerous claims for E/M services provided by Dr. Pavelock are not covered at any level. With respect to other claims for E/M services, the MAC concludes, the services cannot be covered at the level billed by Dr. Pavelock, but may be covered at down-coded levels. The MAC magnifies these fundamental errors by applying its flawed reasoning to a statistical sample of claims and extrapolating an estimated level of overpayment. The MAC further errs by including in the statistical sample pre-2008 claims for which Dr. Pavelock is "without fault" under the statute in effect at the time of the claim and the initial determination of overpayment. *See* 42 U.S.C. § 1395gg(b) (2012).

The MAC Decision II cannot stand. First, contrary to the plain meaning of CMS regulations at 42 C.F.R. § 405.1062, the MAC binds the ALJ to non-binding guidance requiring in-person consultations with patients. Second, with respect to services it down-coded, the MAC's decision is not supported by substantial evidence and must be set aside. *See* 42 U.S.C. § 1395y(a)(1)(A). Third, the inclusion of claims in the statistical sample for which Dr. Pavelock is without fault is contrary to the plain language of 42 U.S.C. § 1395gg(b) (2012).

THE PARTIES

1. Defendant Sylvia Burwell (the "Secretary") is the Secretary of the Department of Health and Human Services of the United States, whose responsibilities include implementing Title XVIII of the Act, as amended, 42 U.S.C. § 1395, *et seq.* (the "Medicare program"), through the Centers for Medicare and Medicaid Services ("CMS"). She is named as a defendant herein in her official capacity.

2. Plaintiff Richard M. Pavelock, M.D. is a resident of Statesville, North Carolina and holds a license to provide medical services in the State of North Carolina ("Dr. Pavelock").

JURISDICTION AND VENUE

3. This Court has jurisdiction under 28 U.S.C. § 1331 (federal question), Section 1869(b) of the Social Security Act, 42 U.S.C. § 1395ff(b)(2) (establishing the right to judicial review of any decision by a review entity selected by the Departmental Appeals Board for purposes of making determinations with respect to benefits under Part A or Part B of the Medicare program), and 28 U.S.C. § 2201 (declaratory judgment).

4. Venue in this District is proper pursuant to 42 C.F.R. § 405.1136(b) because Dr. Pavelock's principal place of business is located in this District.

5. The amount in controversy exceeds $1,460.00, the minimum requirement for jurisdiction pursuant to 42 U.S.C. §1395ff(b)(1)(E)(i), as adjusted by the Consumer Price Index, pursuant to 42 U.S.C. §1395ff(b)(1)(E)(iii).

ADMINISTRATIVE EXHAUSTION

6. Medicare appeals regulations allow for five levels of appeal: (1) redetermination; (2) reconsideration; (3) ALJ hearing; (4) MAC review; and (5) judicial review in a United States District Court.

7. In a letter dated January 23, 2012, AdvanceMed, the Zone Program Integrity Contractor ("ZPIC"), determined that Dr. Pavelock had been overpaid in the amount of $532,941.00. This determination was made based on a post-payment review of a statistical sampling of Dr. Pavelock's claims for E/M services.

8. Pursuant to 42 C.F.R. § 405.940, Dr. Pavelock requested a redetermination of the ZPIC's initial overpayment determination, on February 28, 2012. The Medicare contractor Palmetto GBA ("Palmetto") issued a redetermination decision on June 13, 2012 finding that Dr. Pavelock had been overpaid in the amount of $516,627.

9. In a letter dated August 8, 2012, Dr. Pavelock requested reconsideration of Palmetto's redetermination by Q2Administrators, LLC, the Medicare Qualified Independent Contractor (the "QIC"). *See* 42 C.F.R. § 405.960. In a letter dated September 22, 2012, the QIC issued its decision.

10. Dr. Pavelock requested a hearing before an Administrative Law Judge in a letter dated November 20, 2012, to challenge the QIC's decision. *See* 42 C.F.R. § 405.1002. This hearing was conducted by telephone on June 6, 2013. The ALJ issued a decision favorable to Dr. Pavelock on May 8, 2014 (the "ALJ Decision I").

11. Medicare's Administrative Qualified Contractor ("AdQIC") referred the ALJ Decision I to the MAC for possible review on the MAC's motion in a letter dated July 3, 2014. On October 6, 2014, the MAC issued the MAC Decision I, remanding the dispute to the ALJ with instructions to issue a new decision.

12. The ALJ, analyzing the evidence and testimony presented at the June 6, 2013 hearing, issued the ALJ Decision II on January 9, 2015.

13. AdQIC again referred the ALJ's decision to the MAC in a letter dated March 9, 2015. The MAC Decision II reversed the ALJ Decision II in part.

14. Having exhausted his administrative remedies, Dr. Pavelock now seeks judicial review pursuant to 42 C.F.R. § 405.1136(a).

FACTUAL BACKGROUND

15. Dr. Pavelock is enrolled as a Medicare supplier and provides physicians' services to Medicare beneficiaries as part of his medical practice.

16. Dr. Pavelock serves a non-traditional group of patients. The patients are inpatients at Medicare ICF/MRs. Each patient has a diagnosis of moderate to profound mental retardation, with one or more secondary diagnoses such as seizure disorder, autism, bipolar disorder, attention deficit hyperactivity disorder, depression and obsessive-compulsive disorder. Due to their underlying medical conditions, these

patients are non-verbal. Each patient has been declared legally incompetent by a North Carolina state court, and the court-appointed guardian has entrusted the patient to the care of the ICF/MR facility and the nurses practicing there.

17. Registered nurses at the ICF/MR facilities provide around-the-clock care for the patients. Because the patients are non-verbal and because the nurse-caregivers are the best and often only source of information about the patients' history and medical condition, Dr. Pavelock's practice is to communicate with nurse-caregivers in order to take patient histories and gather information about the patients' medical condition. This consultation is functionally equivalent to Dr. Pavelock asking the patient pertinent questions about his or her condition and medical history. The nurse-caregivers "stand in the shoes" of the patient when the patient is unable to communicate with Dr. Pavelock. A face-to-face encounter is not necessary in light the consultation with nurse-caregivers and moreover might harm mentally compromised patients as interruptions to the schedules of such patients may trigger agitation and aggressive behavior.

THE SUBMITTED CLAIMS

18. The fifty-three claims forming the statistical sample upon which the overpayment amount was based relate to forty-three patients.

19. Thirteen of the claims forming the statistical sample were paid in 2008. With respect to these claims, AdvanceMed made its 2012 overpayment determination more than three years following the year in which payment was made. These claims included the following:

Patient
K.A. (first date of service)
L.B.
P.B.
E.B. (first date of service)
E.B. (second date of service)
R.C.
A.F.
G.G. (first date of service)
C.P. (first date of service)
B.P.
R.R.
S.R.
S.T.

20. Before the ALJ, Dr. Pavelock presented expert testimony regarding the coding of E/M services from expert witness Dottie Koehler. Ms. Koehler testified that she reviewed each claim submitted by Dr. Pavelock that AdvanceMed had down-coded in its initial denial. She also testified that the level of service provided to each specific patient supported the code that Dr. Pavelock had initially billed.

21. Dr. Pavelock also submitted documentary evidence to the ALJ regarding the claims made for E/M services for each of the patients and service dates at issue. The evidence demonstrated that, for each patient, Dr. Pavelock did not conduct an in person examination; instead he consulted with nurse-caregivers.

22. With respect to the patients and service dates in the table below, Dr. Pavelock submitted evidence demonstrating that he conducted a detailed interval history and used medical decision-making of moderate complexity. In each instance, Dr. Pavelock spent at least 25 minutes with the nurse-caregiver or other staff members.

Patient
M.B. (first date of service)
M.B. (second date of service)
M.G.2

J.H.
C.M.
E.W.1

23. With respect to the patients and service dates in the table below, Dr. Pavelock submitted evidence demonstrating that he conducted a detailed interval history and used medical decision-making of moderate complexity. In each instance, Dr. Pavelock spent at least 40 minutes with the nurse-caregiver or other staff members.

Patient
K.A. (second date of service)
W.B.
L.B.
P.B.
D.B.
V.C.
A.F.
L.F.
G.G. (first date of service)
G.G. (second date of service)
M.G.1
R.H.1 (first date of service)
R.H.1 (second date of service)
B.H.
R.H.2 (first date of service)
R.J.
J.J.
J.L.
T.M. (first date of service)
L.O.
S.T.
T.V.
E.W.2

24. Dr. Pavelock submitted evidence demonstrating that he conducted a comprehensive interval history and used medical decision-making of high complexity on patient A.S. Dr. Pavelock spent over 35 minutes with the nurse-caregiver or other staff members on this occasion.

25. Dr. Pavelock submitted evidence demonstrating that he conducted an expanded problem-focused history and used medical decision-making of low complexity on patient R.H.2 on the second date of service associated with that patient. Dr. Pavelock spent at least 25 minutes with the nurse-caregiver or other staff members on this occasion.

26. With respect to the patients and service dates in the table below, Dr. Pavelock submitted evidence demonstrating that he conducted a problem-focused history and used straightforward medical decision-making. In each instance, Dr. Pavelock spent at least 15 minutes with the nurse-caregiver or other staff members.

Patient
K.A. (first date of service)
R.C.
L.D.
E.E.
A.L. (first date of service)
A.L. (second date of service)
T.M. (second date of service)
B.P.
R.R.
S.R.
E.T. (first date of service)
E.T. (second date of service)

27. With respect to the patients and service dates in the table below, Dr. Pavelock submitted evidence demonstrating that he conducted a problem-focused history and used straightforward medical decision-making. In each instance, Dr. Pavelock spent at least 10 minutes with the nurse-caregiver or other staff members.

Patient
J.B.1
J.B.2
E.B. (first date of service)

E.B. (second date of service)
M.L.
C.P. (first date of service)
C.P. (second date of service)
J.P.
J.S.
J.V.

28. Based on this evidence, on remand the ALJ issued the January 9, 2015 ALJ Decision II, which was largely favorable to Dr. Pavelock.

29. The ALJ considered non-binding guidance in the Medicare Benefit Policy Manual (the "Manual") that physicians' services (including E/M services) should involve the "physician either examin[ing] the patient in person or . . . visualiz[ing] some aspect of the patient's condition without the interposition of a third person's judgment." Medicare Benefit Policy Manual, Ch. 15, § 30.A. After examining the condition of each patient individually, the ALJ reasoned that because "communication with a physician as to her [or his] condition would be difficult to impossible," "a more elastic definition of physician service" was appropriate and Dr. Pavelock's practice of gathering a history through patient caregivers did not undercut his claims for E/M reimbursement. The ALJ specifically stated: "The undersigned spend an exhaustive amount of evaluation of the services rendered employing the description of E/M services, and departs from the 1997 guidelines onto [*sic*] to the extent that the subject decision adopts an emphasis on consultations with care teams in an effort to visualize the patient's condition without the need of re-injury with interference with patients' schedules." *Id.* at 77.

30. The QIC denied the claims in the table below based solely on the lack of a face-to-face examination. The ALJ reversed those denials and found the services were reimbursable at the level initially billed by Dr. Pavelock:

Patient
K.A. (first date of service)
J.B.1
J.B.2
E.B. (first date of service)
E.B. (second date of service)
R.C.
L.D.
E.E.
A.L. (first date of service)
A.L. (second date of service)
M.L.
T.M. (second date of service)
B.P.
J.P.
R.R.
S.R.
J.S.
S.T.
E.T. (first date of service)
J.V.

31. The QIC held that the claims listed in the table below were reimbursable, but only at levels down-coded from those Dr. Pavelock had initially billed. After analyzing the individual facts, the ALJ reversed the QIC with respect to these claims and found the claims in the table below were reimbursable E/M services at the level initially billed by Dr. Pavelock. Specifically, the ALJ analyzed whether the medical history taken by Dr. Pavelock and the medical decision-making employed by Dr. Pavelock justified the level billed.

Patient
K.A. (second date of service)
W.B.

P.B.
V.C.
A.F.
L.F.
G.G. (first date of service)
G.G. (second date of service)
M.G.1
M.G.2
R.H.1 (first date of service)
R.H.1 (second date of service)
J.H.
B.H.
R.J.
J.J.
J.L.
T.M. (first date of service)
C.M.
L.O.
A.S.
T.V.
E.W.1
E.W.2

32. The QIC held that the claims listed in the table below were reimbursable, but only at levels down-coded from those Dr. Pavelock had initially billed. After analyzing the individual facts, the ALJ upheld the QIC with respect to the claims and found the claims in the table below were reimbursable E/M services , but at down-coded levels.

Patient
L.B.
M.B. (first date of service)
M.B. (second date of service)
D.B.
R.H.2 (first date of service)

33. Without individual examination, the ALJ found that a very few claims, listed in the table below, were not medically necessary and were not reimbursable at any level.

Patient
E.B. (second date of service)
A.S.

34. On June 5, 2015, the MAC issued the MAC Decision II which reversed the ALJ Decision II in part.

35. The MAC rejected the ALJ's analysis of the requirement of a face-to-face consultation in these circumstances and found that many of the E/M services did not meet the Manual's non-binding definition of covered physicians' services due to the lack of a face-to-face encounter. Despite the explanation provided by the ALJ, the MAC found that the ALJ "failed to give full consideration" to the Manual's provisions. MAC Decision II, at 12. The MAC Decision II therefore held that each of the claims identified in Paragraph 30 could not be covered at any level.

36. The MAC Decision II's rejection of the ALJ's "more elastic" definition of physicians' services based on the provisions of the Manual was inconsistent with plain language of the federal regulations providing that ALJs are not bound by the Manual provided that they explain their reasoning in departing. *See* 42 C.F.R. § 405.1062. The ALJ explained his departure from the non-binding guidance in the Manual, both with respect to each beneficiary at issue and as a general matter.

37. With respect to the claims identified in Paragraphs 31 and 32, the MAC reversed the ALJ's January 9, 2015 decision and found that the claims could only be covered at down-coded levels. The MAC came to this conclusion despite the weight of the evidence submitted by Dr. Pavelock and the expert testimony provided by Ms. Koehler that various E/M services met the requirements of the codes billed. The MAC

Decision II improperly failed to take into account the medical complexity of Dr. Pavelock's patient population in coming to this conclusion. Dr. Pavelock provided records supporting the claims at the level billed and presented expert testimony supporting these claims. The MAC Decision II rests on an incorrect assumption that Dr. Pavelock could not provide E/M services at particular levels in the absence of face-to-face encounters and was not supported by substantial evidence. *See* 42 U.S.C. § 1395y(a)(1)(A).

38. Without discussion, The MAC Decision II included in the extrapolation sample pre-2008 claims. At the relevant time, federal law prohibited CMS from recouping overpayments for overpayment determinations made "subsequent to the third year following the year in which payment for the claim is made." 42 U.S.C. § 1395gg(b) (2012). The determination of the overpayment was not until 2012, meaning that claims paid in 2008 cannot be recouped and cannot be included in the extrapolation sample. The MAC Decision II was contrary to the unambiguously expressed intent of Congress by including in the sample these pre-2008 claims.

COUNT I
VIOLATION OF THE APA

39. The foregoing paragraphs are incorporated by reference as though specifically re-alleged herein.

40. Defendant's rejection of Dr. Pavelock's submitted claims through the MAC Decision II was improper under the Medicare laws and regulations.

41. The MAC exceeded the authority granted to it by the Medicare statutes by rejecting the ALJ's analysis of non-binding guidance materials, by rendering a decision not supported by substantial evidence and by including pre-2008 claims in the extrapolation sample.

42. The MAC acted arbitrarily, capriciously and abused its discretion when it exceeded the authority granted to it by the Medicare statute.

43. The Defendant's action must be set aside under the APA because the agency action was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

COUNT II
VIOLATION OF THE MEDICARE REGULATIONS (ALJ'S REJECTION OF MANUAL GUIDANCE)

44. The foregoing paragraphs are incorporated by reference as though specifically re-alleged herein.

45. The Medicare regulations require ALJs to consider, but not necessarily to follow, certain non-binding agency guidance. The Defendant, through the MAC, has failed to follow the requirements of the Medicare regulations by rejecting the ALJ's thorough consideration of the provisions of the Manual.

46. The Defendant's action must be set aside under the APA because the agency action was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

COUNT III
VIOLATION OF THE MEDICARE STATUTE (PRE-2008 CLAIMS)

47. The foregoing paragraphs are incorporated by reference as though specifically re-alleged herein.

48. The Defendant, through the MAC, has failed to follow the requirements of the Medicare statute by including in the extrapolation sample claims paid in 2008.

49. At the relevant time, federal law prohibited CMS from recouping overpayments for overpayment determinations made "subsequent to the third year following the year in which payment for the claim is made." 42 U.S.C. § 1395gg(b) (2012).

50. The Defendant's action must be set aside under the APA because the agency action was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

COUNT IV
VIOLATION OF THE MEDICARE STATUTE (FAILURE OF THE MAC TO CONSIDER THE SUBSTANTIAL EVIDENCE)

51. The foregoing paragraphs are incorporated by reference as though specifically re-alleged herein.

52. The Defendant, through the MAC, has failed to consider the substantial evidence which demonstrates that the claims are reimbursable at the level initially billed by Dr. Pavelock.

53. The Defendant's action must be set aside under the Medicare statutes because the agency action was not supported by substantial evidence. 42 U.S.C. § 1395y(a)(1)(A).

PRAYER FOR RELIEF

WHEREFORE, Dr. Pavelock respectfully requests the following relief:

1. Issue a declaratory judgment that the Defendant acted arbitrarily, capriciously, contrary to law, and abused its discretion in ignoring the ALJ's findings of fact.

2. Reverse the MAC Decision II and issue a decision finding the claims at issue reimbursable at the levels initially billed by Dr. Pavelock.

3. Enter an order awarding Dr. Pavelock reasonable attorneys' fees and costs of prosecuting this action.

4. Enter an order awarding prejudgment interest, pursuant to 42 U.S.C. § 1395ff(b)(2)(C)(iv) and 42 C.F.R. § 405.378(j)(4), the common law, and all other applicable laws, statutes and regulations.

5. Grant such other and further relief as the Court deems just and equitable.

Dated August 5, 2015

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